DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 10, 2015

MAKO Surgical Corporation
Mr. Jonathan Reeves
Principal Regulatory Affairs Specialist
2555 Davie Road
Fort Lauderdale, Florida 33317

Re: K150307
Trade/Device Name: RESTORIS™ Multicompartmental Knee (MCK) System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: NPJ, HSX, HRY, KRR, OIY
Dated: January 29, 2015
Received: February 9, 2015

Dear Mr. Reeves:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150307

Device Name
RESTORIS™ Multicompartmental Knee (MCK) System

Indications for Use *(Describe)*
RESTORIS™ Multicompartmental Knee (MCK) System is indicated for single or multi-compartmental knee replacement used in conjunction with RIO®, the Robotic Arm Interactive Orthopedic System, in individuals with osteoarthritis or posttraumatic arthritis of the tibiofemoral and/or patellofemoral articular surfaces. The specific knee replacement configurations include:

- Medial unicondylar
- Lateral unicondylar
- Patellofemoral
- Medial bi-compartmental (medial unicondylar and patellofemoral)

RESTORIS™ Multicompartmental Knee (MCK) System is for single use only and is intended for implantation with bone cement.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

Submitter: MAKO Surgical Corp.

Address: 2555 Davie Road, Fort Lauderdale, FL 33317

Phone number/ Fax Number: (Ph) 954-628-0665; (F) 954-927-0446

Contact Person: Jonathan Reeves

Date Prepared: January 29, 2015

Proprietary Name: The RESTORIS™ Multicompartmental (MCK) Knee System

Common Name: Partial Knee System

Classification: Class II

Product Codes/Classification #:

Code of Federal Regulations	Product code	Description
21 CFR 888.3520	HSX	Knee joint femorotibial metal/polymer non constrained cemented prosthesis
21 CFR 888.3530	HRY	Knee joint femorotibial metal/polymer semi constrained cemented prosthesis
21 CFR 888.3540	KRR	Knee joint patellofemoral polymer/metal semi constrained cemented prosthesis
21 CFR 888.3560	NPJ	Knee joint patellofemorotibial polymer/metal/polymer semi constrained cemented prosthesis
21 CFR 888.3560	OIY	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.

Reason for 510(k) submission: Special 510(k): Device modification with no change to fundamental scientific technology or intended use

Device Modification:

- Addition of Highly Cross-linked UHMWPE (X3) onlay tibial insert
- Gas Plasma Sterilization
- Packaging

Device Description:

RESTORIS™ Multicompartmental Knee (MCK) System is an implant system designed to be used with MAKO's Robotic Arm Interactive Orthopedic System (RIO). It is composed of a unicompartmental implant system (RESTORIS™ MCK Uni) and a patellofemoral implant system (RESTORIS™ MCK PF).

- RESTORIS™ MCK Uni:
  - Unicompartmental femoral condyle components
  - Unicompartmental tibial onlay components (tibial baseplate and tibial onlay insert)
  - Unicompartmental tibial inlay components

- RESTORIS™ MCK PF:
  - Patellofemoral trochlear components
  - Patella components

The RESTORIS™ MCK Uni is designed for use when load bearing ROM is expected to be less than or equal to 155 degrees. In RESTORIS™ MCK combinations where multi-compartmental areas are being treated, the RESTORIS™ MCK components were designed with 3 mm of gap between the components to ensure that the components do not interfere.

Intended Use:
Restoris™ Multicompartmental Knee (MCK) System is indicated for single or multi-compartmental knee replacement used in conjunction with RIO®, the Robotic Arm Interactive Orthopedic System, in individuals with osteoarthritis or post-traumatic arthritis of the tibiofemoral and/or patellofemoral articular surfaces. The specific knee replacement configurations include:

- Medial unicondylar
- Lateral unicondylar
- Patellofemoral
- Medial bi-compartmental (medial unicondylar and patellofemoral)

The RESTORIS™ Multicompartmental Knee System is for single use only and is intended for implantation with bone cement.

Substantial Equivalence:
The RESTORIS™ Multicompartmental Knee System is substantially equivalent to the following 510(k) cleared devices.

Device Name	Manufacturer	510(k) #
RESTORIS Multicompartmental Knee System	MAKO	K133039

Technological Characteristics:
The RESTORIS™ Multicompartmental Knee System is similar to legally marketed devices listed previously in that they share the same indications for use, are manufactured from the same or similar material, have same design/technological characteristics and have performance characteristics adequate to withstand anticipated physiological loading.

Performance Data:
The RESTORIS™ Multicompartmental Knee System has been evaluated through non-clinical performance testing for:

- Insert Snaplock Strength
- Tibial Insert / Baseplate Micromotion
- Tibio-Femoral Range of Motion
- Tibio-Femoral Instability
- Tibio-Femoral Contact Area and Stress
- Tibial Insert Fatigue
- Tibial Insert Wear
- Packaging Validation
- Gas Plasma Sterilization Validation
- 5 Year Aging

Conclusions of Non-clinical Data:
The results of performance testing indicated the device performed within the intended use and
did not raise any new safety and efficacy issues. The device was found to be substantially equivalent to the predicate devices.

Summary of Design Control Activities:
The risk analysis activities for this device modification include a risk management plan, hazard analysis and Failure Modes and Effects Analysis (FMEAs). Based upon the review of this data and information obtained through verification and validation activities, there are no unacceptable levels of risks that have been identified resulting from the device modification.